IMPROVING THE MEASUREMENT OF BLOOD GLUCOSE BY PORTABLE BLOOD GLUCOSE MONITORING SYSTEMS

Description of Project

- Goal
  People with diabetes and their health care providers rely on the results reported by portable blood glucose monitoring systems to make treatment decisions. Improper treatment can result if the performance of these systems is not reliable. The goal of the program is to evaluate and determine the variability among blood glucose monitoring systems and to develop a standardization program to improve and normalize results among these systems.
- Approach
  To assess the magnitude of variability among monitoring systems, a monitor comparison study using fresh capillary blood specimens will be conducted. A reference method that allows the measurement of capillary blood used by glucose monitoring systems and other blood specimens such as serum, plasma, and interstitial fluid will be developed that will function as the reference point for monitoring systems. With this method, values can be assigned to a reference material, which then can be used by manufacturers to calibrate their monitoring systems, or to verify calibration. This includes the development of secondary reference material that is appropriate for glucose monitoring systems. Finally, assistance will be provided to manufacturers, the clinical and public health community on glucose measurements to help increase awareness of the problem of glucose measurements and improve operator related problems.

Accomplishments

- Developed, organized, and completed a pilot study to examine the among-finger variability for blood glucose measurements.
- Developed, organized, and completed a study to examine the variability among popular handheld blood glucose monitoring systems.
- Developed and characterized a gas chromatography isotope dilution mass spectrometry (GC-IDMS) method for quantitating glucose in whole blood, serum, plasma and interstitial fluid (for use as a reference method).
- Carried out investigations on technologies to create secondary reference materials by:
  - assessing the reliability of capillary collection devices;
  - assessing existing quality control materials;
  - initiating a research effort to develop a secondary reference material for whole blood glucose in collaboration with outside partners.
- Conducted collaborative research with Dr. Mark Prausnitz at Georgia Institute of Technology, Atlanta, to assess the use of micro needles to collect interstitial fluid for glucose monitoring.
  - A comparison between interstitial fluid obtained through micro needles and whole blood was performed.

    - Completed a comparison between a monitor and our reference method using interstitial fluid.
- Validated a capillary collection procedure for its suitability for fresh specimen split comparison studies.
- Performed an instrument comparison study using the GC-IDMS reference method, a clinical laboratory instrument, and a glucose meter. The comparison was performed using different matrices (plasma, whole blood, capillary blood).
- Provided scientific and technical assistance to organizations, manufacturers and the clinical and public health communities on issues related to glucose measurements by:
    - Organizing a session entitled "Glucose, A1C, and lipids: understanding the numbers behind quality improvement" held at the Diabetes Translation Conference, St. Louis, MO, May 6-9, 2002.
    - Organizing and convening an educational session on glucose testing at the annual meeting of the American Association for Clinical Chemistry July 2002.
- Publications and Presentations:
    - Porter KH, Vesper HW, Myers GL, Sampson EJ. Development of a national standardization program to improve the measurement of blood glucose by portable glucose monitors. Poster Presentation, Annual Meeting of the American Diabetes Association, June 2002.
    - Porter KH, Myers GL. Interstitial fluid and a new era of glucose monitoring. Oral Presentation, Annual Meeting of the American Association for Clinical Chemistry, July 2002.
    - Vesper HW, Porter KH, Archibold E, Myers GL. Candidate Reference Method for Measuring Glucose in Capillary Whole Blood and Serum. Poster Presentation, Annual Meeting of the American Association for Clinical Chemistry, July 2003.
    - Vesper HW, Porter KH, Archibold E, Myers GL. Candidate Reference Method for Measuring Glucose in Capillary Whole Blood and Serum. Poster Presentation, annual meeting of the American Association for Clinical Chemistry, July 2003.
    - Kimberly MM, Vesper HW, Caudill SP, Ethridge SF, Archibold E, Porter KH, Myers GL. Glucose Monitor Variability Project. Poster Presentation, Third Annual Diabetes Technology Meeting, November 2003.

Future directions

- Develop secondary reference material with appropriate stability for glucose and sufficient commutability across monitoring systems to facilitate common calibration of manufacturer's monitoring systems and appropriately assess calibration of these systems over time. This includes:
    - Screening for potential materials;
    - Characterization and validation of candidate materials;
    - Introduction and field testing of candidate materials;

- Assess the impact of this standardization effort on monitor variability through special designed studies;
- Publish the results of the pilot study to examine the among-finger variability for blood glucose measurements;
- Publish the results of the study to examine the variability among popular handheld blood glucose monitoring systems;
- Publish the results of the capillary collection procedure for fresh sample comparisons;
- Publish the results of the instrument comparison with fresh capillary samples;
- Publish the results of the microneedle studies.

Participants

Sponsor: Centers for Disease Control and Prevention

For further information on this project, please contact:

Dr. Mary Kimberly
CDC
Phone: (770) 488-4683
E-mail: MKimberly@cdc.gov